UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
CHICAGO DIVISION

SELENA FELICIANO, Individually, and as Parent and Natural Guardian of G.D., an infant, Plaintiffs, v. ABBOTT LABORATORIES, INC., Defendant.	Civil Action No.: 1:22-cv-1439 **COMPLAINT AND JURY TRIAL DEMANDED**

Plaintiff SELENA FELICIANO, Individually, and as Parent and Natural Guardian of G.D., an infant ("Plaintiff"),[1] by and through her undersigned counsel, hereby submits the following Complaint and Demand for Jury Trial against Defendant ABBOTT LABORATORIES, INC. ("Abbott" or "Defendant") and alleges upon information and belief the following:

NATURE OF THE ACTION

1. Plaintiff brings this action on behalf of herself and G.D., an infant, seeking damages for the severe and catastrophic injuries suffered by G.D. as a direct and proximate result of consuming Similac NeoSure, a cow's milk-based nutrition product manufactured by Abbott. G.D started feeding with Similac NeoSure at Good Samaritan Hospital in West Islip, New York in the hospital's neonatal intensive care unit ("NICU") after he was born preterm at twenty-six (26) weeks. As a direct and proximate result of consuming Similac NeoSure, G.D. developed necrotizing enterocolitis ("NEC"), a devastating gastrointestinal condition associated with cow's

[1] Pursuant to Federal Rule of Civil Procedure ("FRCP") 5.2(a)(3), this document contains only the identifying initials of G.D., an infant.

milk-based nutrition products, which required him to undergo multiple surgical interventions and resulting in life-altering limitations.

2. NEC is the most lethal gastrointestinal disorder affecting preterm infants, and is characterized by disruption of the intestinal barrier leading to intestinal necrosis, multi-system organ failure and death. The current treatment regimen for infants with NEC includes cardiorespiratory support, nasogastric decompression, broad-spectrum antibiotics, cessation of enteral feedings, and surgical intervention involving the removal of necrotic intestine or peritoneal drainage, which is indicated when NEC causes a bowel perforation or fails to improve with medical management.

3. Years before G.D. was exposed to Similac NeoSure and developed NEC, Abbott was aware, or should have been aware, of the overwhelming body of scientific evidence and research confirming that cow's milk-based nutrition products, like Similac NeoSure, cause or substantially increase the risk of NEC in preterm infants. Although Abbott knew, or should have known, about the unreasonable and substantial adverse risks its cow's milk-based products posed to preterm infants, it negligently, recklessly, or intentionally failed to make these products safer or adequately warn consumers or the health care community of their products' true risks.

4. Instead, Abbott has undermined the science connecting cow's milk-based nutrition products to NEC and unduly influenced the perception of the public and medical community through aggressive and misleading marketing campaigns promoting products like Similac NeoSure as safe and equivalent or superior alternatives to human milk for *all* infants, which it knew was false.

5. Accordingly, and as a direct and proximate result of Abbott's wrongful conduct in researching, developing, designing, manufacturing, marketing, distributing, and selling Similac

NeoSure, and its failure to warn consumers such as Plaintiff or G.D.'s physicians and health care providers regarding the known or foreseeable risks of cow's milk-based nutrition products, G.D. developed NEC and suffered catastrophic injuries and life-altering injuries.

THE PARTIES

PARTY PLAINTIFF

6. Plaintiff Selena Feliciano, a natural person, is domiciled in and a citizen of the State of New York and resides in Suffolk County, New York.

7. Plaintiff Selena Feliciano is the Parent and Natural Guardian of G.D., an infant.

8. G.D., a natural person and infant, is domiciled in and a citizen of the State of New York. G.D. was born prematurely at Good Samaritan Hospital in West Islip, New York in 2020.[2]

9. G.D. developed NEC after being fed Similac NeoSure while in the NICU at Good Samaritan Hospital in West Islip, New York.

10. At all relevant times, G.D. used Similac NeoSure for the purpose which Abbott researched, developed, designed, manufactured, marketed, distributed, sold, and otherwise intended it for, namely, as a source of nutrition for preterm infants.

11. As a result of using Similac NeoSure, G.D. developed NEC, requiring multiple surgeries, and suffered severe personal injuries that would not have occurred but for the defective nature of Similac NeoSure or Abbott's failure to adequately warn Plaintiff or G.D.'s physicians or health care providers of the serious health risks associated with the use of Similac NeoSure by preterm infants.

[2] Pursuant to FRCP 5.2(a)(2), this document contains only the year of G.D.'s birth.

PARTY DEFENDANT

12. Abbott is a corporation with its principal place of business in the State of Illinois at 100 Abbott Park Road, Abbott Park, Illinois 60064.

13. At all relevant times, Abbott is a corporation duly organized, incorporated, and existing under the laws of the State of Illinois.

14. Abbott is a multinational health care company that researches, develops, designs, manufactures, markets, distributes, and sells nutrition products, including infant formula under the Similac brand name, among other products, throughout the United States and the world.

15. At all relevant times, Abbott researched, developed, designed, manufactured, marketed, distributed, and sold cow's milk-based nutrition products, including the cow's milk-based formula used by G.D. under the brand name Similac NeoSure.

JURISDICTION AND VENUE

16. This is an action for damages which exceeds the sum of $75,000, exclusive of costs, interest, and attorneys' fees.

17. This Court has subject matter jurisdiction over this case pursuant to 28 U.S.C. §1332, as complete diversity exists because Plaintiff and Abbott are citizens of different states and the amount in controversy in this action as a result of Abbott's researching, developing, designing, manufacturing, marketing distributing, and selling of cow's milk-based nutrition products, including Similac NeoSure, and failure to warn of the serious and life-threatening risks of these products, substantially exceeds $75,000.00.

18. This Court has specific personal jurisdiction over Abbott, because Abbott regularly transacts business in the State of Illinois by engaging in the researching, developing, designing,

manufacturing, marketing, distributing, or selling of cow's milk-based nutrition products, amongst other products, including the Similac NeoSure used by G.D.

19. Abbott also derives substantial revenue from their business transactions in the State of Illinois and has purposely availed itself of the privilege of doing business in the State of Illinois.

20. Abbott reasonably anticipated, or should have reasonably anticipated, being subjected to specific personal jurisdiction in the State of Illinois as a result of its actions in researching, developing, designing, manufacturing, marketing, distributing, or selling, cow's milk-based nutrition products, amongst other products, in the State of Illinois, including the Similac NeoSure formula used by G.D.

21. Abbott has sufficient minimum contacts with the State of Illinois such that subjecting it to specific personal jurisdiction in this state does not offend traditional notions of fair play and substantial justice and comports with due process.

22. Venue in this Court is proper pursuant to 28 U.S.C. §§1391(a) and (b) because Abbott resides in this judicial district and a substantial part of the events or omissions giving rise to Plaintiff's claims occurred in this District. Venue is also proper in this Court pursuant to 28 U.S.C. §1965(a) because Abbott is headquartered in this District and transacts substantial business in this District.

FACTUAL ALLEGATIONS

A. Background – Nutrition is Essential for Preterm Infants.

23. The World Health Organization ("WHO") defines preterm infants as babies born alive before 37 completed weeks of gestation, and identifies certain subcategories of preterm based

on gestational age including, moderate to late preterm from 32 to 37 weeks; very preterm from 28 to 32 weeks; and extremely preterm from less than 28 weeks [3]

24. Approximately 15 million infants are born preterm each year, and in almost all countries with reliable data, preterm birth rates are increasing. Globally, prematurity is the leading cause of death in children under the age of 5 years old, and the inequalities in survival rates around the world are stark. In low-income settings, half of the infants born at or below 32 weeks die due to a lack of feasible and cost-effective care. In high-income settings, almost all of these infants survive. However, in middle-income settings, the suboptimal use of technology causes an increased burden of disability among preterm infants who survive the neonatal period.[4]

25. Proper nutrition is crucial for preterm infants, and especially so for the growth and healthy development of low-birth-weight preterm infants.[5] Among preterm infants, poor nutrition is associated with numerous adverse health outcomes, including poor head growth, which results in poor psychomotor and mental skills, higher rates of cerebral palsy, and autism.[6] Impaired weight and growth in preterm infants is also significantly associated with adverse neurodevelopmental outcomes later in life.[7]

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[3] *Preterm birth*, World Health Organization (Feb. 19, 2018), https://www.who.int/news-room/fact-sheets/detail/preterm-birth (last accessed Dec. 29, 2021).

[4] *Id.*

[5] Kumar, R Kishore et al. *Optimizing Nutrition in Preterm Low Birth Weight Infants-Consensus Summary*, Frontiers in Nutrition, 4:20, 2 (May 26, 2017).

[6] Lee KA, Hayes BC. *Head size and growth in the very preterm infant: a literature review*, Res Rep Neonatol, 2015:1, 1 (Jan. 6, 2015).

[7] Vinall J, Grunau RE, Brant R, Chau V, Poskitt KJ, Synnes AR, Miller SP. *Slower postnatal growth is associated with delayed cerebral cortical maturation in preterm newborns*, Sci Transl Med., 5:168, 168 (Jan. 16, 2013).

26. Historically, three types of nutrition sources have served preterm infants: parenteral nutrition for feed intolerance, such as a feeding tube; human milk, whether it is mother's own milk or donor milk; and cow's milk-based formulas and fortifiers such as Similac NeoSure.

27. Nevertheless, decades of scientific data and research confirm that feeding preterm infants cow's milk-based formula results in a significant increase in the risk of developing NEC versus human milk, donor milk, or human milk-based fortifier feeding, and for preterm infants, the life-threatening adverse risks associated with consuming cow's milk-based nutrition products far outweigh any benefit.

B. Overwhelming Scientific Evidence Links Cow's Milk-Based Formulas and NEC

28. As early as 1990, a prospective, multicenter study conducted with 926 preterm infants found that NEC was 6 to 10 times more common in exclusively formula-fed infants than in those fed breast milk alone, and three times more common than in those who received formula plus breast milk. As to babies born at more than 30 weeks gestation, the study confirmed that NEC was rare in those whose diet included breast milk, but was 20 times more common in those fed formula only.[8]

29. In a study published in 2007 comparing the outcomes of 1,587 infants pre and post initiation of a feeding protocol providing an exclusive human milk-based diet, researchers stated that "[t]he use of an exclusive HUM [human] diet is associated with significant benefits for extremely premature infants <1259 g BW" including "…decreased NEC rates…" The researchers

[8] A. Lucas, T. Cole. *Breast Milk and Neonatal Necrotizing Enterocolitis*, The Lancet, 336:8730-8731, 1519 (Dec. 22, 1990).

further concluded that "…while evaluating the benefits of using an exclusive HUM-based protocol, it appears that there were no feeding-related adverse outcomes." [9]

30. In a study published in 2010, which evaluated the health benefits of an exclusive human-milk based diet compared with a diet of human milk and bovine [cow] milk-based products among 207 extremely premature infants, researchers concluded that "[f]or extremely premature infants, an exclusively human-milk based diet is associated with significantly lower rates of NEC and surgical NEC when compared with a mother's milk-based diet that also includes bovine milk-based products."[10] The researchers found a reduction in NEC of 50% and surgical NEC of almost 90% in infants fed an exclusive human milk diet compared with a diet containing cow's milk-based products.[11]

31. In 2011, the United States Surgeon General published a report titled, "The Surgeon General's Call to Action to Support Breastfeeding" ("Surgeon General report"), which stated that "for vulnerable premature infants, formula feeding is associated with higher rates of [NEC];" that premature infants who are not breast fed are actually 138% more likely to develop NEC; and the use of human donor milk, as an alternative to formula feeding, "may have the potential to prevent some cases of NEC." [12]

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[9] Hair, A. B., Peluso, A. M., Hawthorne, K. M., Perez, J., Smith, D. P., Khan, J. Y., O'Donnell, A., Powers, R. J., Lee, M. L., & Abrams, S. A. *Beyond Necrotizing Enterocolitis Prevention: Improving Outcomes with an Exclusive Human Milk-Based Diet*, Breastfeeding Medicine, 11:2, 74 (2016).

[10] Sullivan, S., et al. *An Exclusively Human Milk- Based Diet Is Associated with a Lower Rate of Necrotizing Enterocolitis than a Death of Human Milk and Bovine Milk-Based Products*, 156 Journal of Pediatrics, 156:4, 1 (April 2010).

[11] *Id.* at 565.

[12] U.S. Dep't of Health & Human Serv., Off. of Surgeon Gen., *The Surgeon General's Call to Action to Support Breastfeeding*, 27 (2011).

32. The Surgeon General report also warned of the exorbitant financial cost of medical treatment for NEC, and the "substantial burden imposed by NEC on affected families…", stating that "[h]ospitalization for all surgical NEC averages 62 days, at a cost of nearly $300,000 per patient" and "[r]esearchers estimate that across the United States, NEC treatment costs account for 19 [%] of all initial newborn health care costs."[13]

33. In 2012, the American Academy of Pediatrics ("AAP") issued a policy statement directing that all premature infants should be fed an exclusive human milk diet because of the risks of NEC associated with the consumption of cow's milk-based products. The AAP identified evidence from meta-analyses of 4 randomized clinical trials performed over the period of 1983 to 2005 "to support the conclusion that feeding preterm infants human milk is associated with a significant reduction (58%) in the incidence of necrotizing enterocolitis (NEC). The AAP as well discussed "[a] more recent study of preterm infants fed an exclusive human milk diet compared with those fed human milk supplemented with cow-milk-based infant formula products noted a 77% reduction in NEC." [14]

34. Moreover, according to the AAP, "[o]ne case of NEC could be prevented if 10 infants received an exclusive human milk diet, and 1 case of NEC requiring surgery or resulting in death could be prevented if 8 infants received an exclusive human milk diet."[15] Regarding preterm infants, the AAP stated that "[t]he potent benefits of human milk are such that all pre-term

[13] *Id.* at 27.

[14] Arthur I. Eidelman, Richard J. Schanler, Margreete Johnston, Susan Landers, Larry Noble, Kinga Szucs, Laura Viehmann. *Breastfeeding and the Use of Human Milk*, Pediatrics 129:3, 829 (2012).

[15] *Id.*

infants should receive human milk... If the mother's own milk is unavailable ...pasteurized donor milk should be used."[16]

35. In a study published in 2013 in The Journal of Pediatrics regarding the first randomized trial evaluating extremely premature infants feeding exclusively with human milk versus preterm formula, researchers stated that "[i]n extremely preterm infants given exclusive diets of preterm formula vs. human milk, there was a significantly greater duration of parenteral nutrition and higher rate of surgical NEC in infants receiving preterm formula." The researchers concluded "[t]his trial supports the use of an exclusive human milk diet to nourish extremely preterm infants in the neonatal intensive care unit."[17]

36. In a study published in 2014 in Expert Review of Clinical Immunology titled "Evidence-based feeding strategies before and after the development of necrotizing enterocolitis," researchers summarized that "[w]hile the pathogenesis of NEC remains incompletely understood, it is well established that the risk is increased by the administration of infant formula and decreased by the administration of breast milk."[18]

37. In a multi-center study published in 2016, it was reported that "[e]xtremely premature infants who received an exclusive HUM [human milk-based] diet had a significantly

[16] *Id*. at 831.

[17] Cristofalo EA, Schanler RJ, Blanco CL, Sullivan S, Trawoeger R, Kiechl-Kohlendorfer U, Dudell G, Rechtman DJ, Lee ML, Lucas A, Abrams S. *Randomized trial of exclusive human milk versus preterm formula diets in extremely premature infants*. J Pediatr, 163:6, 1592-1595 (Aug. 22, 2013).

[18] Good M, Sodhi CP, Hackam DJ. *Evidence-based feeding strategies before and after the development of necrotizing enterocolitis*, Expert Rev Clin Immunol, 10:7, 874 (July 29, 2014).

lower incidence of NEC and mortality" as well as multiple other improved health outcomes, such as a reduction in sepsis, after implementation of such a feeding protocol.[19]

38. In January 2017, a study published by the American Society for Nutrition reported that "[i]n summary, HM [human milk] has been acknowledged as the best source of nutrition for preterm infants and those at risk for NEC," which the researchers had based on two previous randomized clinical trials finding that an exclusive HM diet results in a lower incidence of NEC and the results from a Cochrane systematic review[20] which "determined that formula significantly increases the risk of NEC."[21]

39. In February 2017, an article published in Seminars in Perinatology titled "Human milk is the feeding strategy to prevent necrotizing enterocolitis!" advised that "[h]uman milk is the preferred diet for preterm infants as it protects against a multitude of NICU challenges, specifically necrotizing enterocolitis." According to the authors, "[p]reterm infants are susceptible to NEC due to the immaturity of their gastrointestinal and immune systems," and "[a]n exclusive human milk diet compensates for these immature systems in many ways such as lowering gastric pH, enhancing intestinal motility, decreasing epithelial permeability, and altering the composition of bacterial flora."

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[19] Hair, Amy, et al. *Beyond Necrotizing Enterocolitis Prevention: Improving Outcomes with an Exclusive Human Milk-Based Diet*, Breastfeeding Medicine, 11:2, 70 (2016).

[20] "The international non-profit Cochrane Collaboration promotes and disseminates information on healthcare interventions...Reviewers systematically search for all evidence related to clinical questions; reports of randomized controlled trials involving human subjects are critically evaluated to enable the reader to quickly determine if the findings apply to a particular patient." Sieving PC. *What is a Cochrane Review?*, ORL Head Neck Nurs., 25:4, 1 (2007).

[21] Shulhan, Jocelyn et al. *Current Knowledge of Necrotizing Enterocolitis in Preterm Infants and the Impact of Different Types of Enteral Nutrition Products*, Adv Nutr., 8:1, 89 (Jan. 2017).

The authors plainly stated that "[i]deally, preterm infants should be fed human milk and avoid bovine [cow] protein."[22]

40. In light of the foregoing, a significant association between cow's milk-based nutrition products and NEC in preterm infants has been clear to formula manufacturers, like Abbott, for decades.

C. Regardless, Abbott Aggressively Markets Similac NeoSure to Obscure its True Risks.

41. Abbott and other influential multinational corporations dominate the infant formula industry, in part, by unduly influencing parents and health care providers to choose cow's milk-based nutrition products over mother's own milk or human donor milk by promoting cow's milk-based formula in such a way as to confuse or limit the ability of health care providers to provide accurate, science-based information about the risks posed by these products to the parents of the infants or ensure that preterm infants in particular receive nutrition that is safe.

42. To that end, Abbott has designed and employed systematic, powerful, and misleading marketing campaigns to deceive parents of preterm infants and health care providers into believing that cow's milk-based nutrition products, such as Similac NeoSure, are safe and equal, or even superior, to human milk and donor milk, and convince them to choose cow's milk-based nutrition products as a first choice for preterm infants, despite knowing about the significant increased risk of NEC associated with these products.

43. Concerns about the marketing of cow's milk-based nutrition products, and the undue influence that manufacturers such as Abbott leverage over consumers and health care providers, are not new. As early as 1979, the WHO and United Nation's International Children's

[22] Maffei D, Schanler RJ. *Human milk is the feeding strategy to prevent necrotizing enterocolitis!*, Seminars in Perinatology, 41:1, 36 (Feb. 2017).

Emergency Fund (UNICEF) held a joint meeting to specifically address concerns regarding the continued marketing of breast-milk substitutes.[23] Reaffirming the critical need to stop manufacturers from marketing and promoting breast-milk substitutes, the Director-General of the WHO concluded this meeting stating "…the campaign against bottle-feed advertising is *unbelievably more important* than the fight against smoking advertisement." [24]

44. In 1981, the decision-making body of the WHO developed the International Code of Marketing of Breast-Milk Substitutes, which required companies to acknowledge the superiority of breast milk and outlawed *any* advertising or promotion of breast milk substitutes to the general public.[25] The International Code of Marketing of Breast-Milk Substitutes expressly prohibits the advertising of breast-milk substitutes, such as Similac NeoSure, or other cow's milk-based nutrition products,[26] including point-of-sale advertising, the giving of samples, or any other promotion device to induce sales directly to consumers at the retail level.[27]

45. Regardless, formula manufacturers have continued to market and promote breast-milk substitutes because without legislative adoption of the International Code of Marketing of

[23] Joint WHO/ UNICEF Meeting on Infant and Young Child Feeding, Geneva 9-12 October 1979: statement recommendations, list of participants, World Health Organization & United Nations Children's Fund (1979), https://apps.who.int/iris/handle/10665/62980 (last accessed March 17, 2022).

[24] Baumslag, N., & Michels, D. L., *Milk, money, and madness: The culture and politics of breastfeeding*. Westport, CT: Bergin & Garvey (1995) at 161 [italics supplied].

[25] International Code of Marketing of Breast-Milk Substitutes, World Health Organization (1981), https://apps.who.int/iris/handle/10665/40382 (last accessed March 8, 2022).

[26] *Id.* at Article 5.2.

[27] *Id.* at Article 5.3.

Breast-Milk Substitutes, which to this day has not occurred in the United States, infant formula advertising has widely continued without pause.

46. Another two decades later, the WHO reported in a 2018 Status Report that "despite ample evidence of the benefits of exclusive and continued breastfeeding for children, women, and society, far too few children are breastfed as recommended" and "a major factor undermining efforts to improve breastfeeding rates is *continued aggressive marketing* of breast-milk substitutes." [28]

47. Notwithstanding the International Code of Marketing of Breast-Milk Substitutes, and the international outcry against the advertising of infant formula, Abbott and other manufacturers have continued marketing infant formula while investing billions of dollars in promotional campaigns that the WHO and UNICEF decried as harmful to global health. A study tracking the statistics of trends and patterns in infant formula sales from 2008 to 2013 estimated that in 2014 alone formula manufacturers spent approximately $4.48 billion dollars on marketing and promotions that directly targeted consumers through online and print advertising and indirectly through health systems, sponsorships of professional organizations and lobbying of policy makers.[29]

48. Abbott and other manufacturers recklessly, negligently, and intentionally have continued to aggressively market and advertise cow's milk-based nutrition products, like Similac NeoSure, to the parents of preterm infants and health care providers, representing that these

[28] *Marketing of Breast-milk Substitutes: Nat'l Implementation of the Int'l Code, Status Report 2018*, World Health Organization (May 2018) [italics supplied].

[29] Baker, P, et al. *Global trends and patterns of commercial milk-based formula sales: is an unprecedented infant and young child feeding transition underway?* Public Health Nutrition, 19:14 (2016).

products are safe for preterm infants, will benefit them, promote their growth, and give them the best chance for survival in a manner that is consistent with accepted science – all the while withholding from parents and health care providers alike critical information regarding the significant risk of NEC and catastrophic injuries.

49. Beginning in 1989, Abbott has continuously perpetuated the myth that health care providers believed its line of Similac products was the "first choice" of physicians, naturally implying that it is the superior choice even compared to human milk. From 1995, Abbott initiated a marketing campaign that actually featured "1st Choice of Doctors" on all its infant formula product labels. In March 1998, a marketing report commissioned by Abbott summarized consumer reactions to its Similac informational advertising pamphlets, and found that the "1st Choice of Doctors" claim scored the highest in terms of the consumer's likelihood to purchase. The report concluded that "[d]octor recommendations and the 'science' behind the formula appeared to drive purchase interest for this concept, as well as other concepts tested," and that the use of similar marketing pieces emphasizing this claim was "highly recommended" and scored very high in convincing consumers that Similac "is the formula doctors prefer."

50. Abbott's marketing campaigns have misleadingly asserted for years that professionals who were knowledgeable had ratified Abbott's products, when they did not, and influenced consumers and health care providers not to think about their choice of product or the true inherent risks which Abbott ensured the omission of from product labeling and instructions, specifically the risk of NEC.

51. In fact, in response to Abbott's "1st Choice of Doctors" claims, Abbott's direct competitor in the infant formula market, Mead Johnson & Company, conducted its own survey to determine the actual takeaway of consumers from Abbott's claims. Mead Johnson's surveyors

concluded that more than 80 percent of consumers understood the "1st Choice of Doctors" claim to convey that a majority of doctors choose or prefer Similac, and more than 40 percent understood the claim as making some claim of product superiority. With respect to the subject of doctors' reasons for choosing or preferring Similac, more than 50 percent of respondents attributed that to their views of the quality or superiority of Similac

52. Independent studies have further shown that infant formula advertising works. In 2010, a content analysis study on health statements made by infant formula manufacturers from 1971 through 1999 in print advertisements published across 87 issues of Parents Magazine - one of the most popular and widely subscribed to parenting magazines in the United States - showed that when the frequency of infant formula advertisements increased, the percentage change in breast-feeding rates reported in the next years generally decreased. The study also found that infant formula manufacturers' websites, printed materials, coupons, samples, toll-free infant feeding information lines, and labels may mislead consumers into purchasing infant formula that appears equivalent or superior to human milk. [30]

53. Consequently, upon information and belief, Abbott's widespread and deceptive marketing campaigns have been intended to not only sell their products, but also influence and confound the perceptions of the public regarding the formulation and quality of cow's milk-based nutrition products in such a way to lessen the likelihood that parents of preterm infants receiving cow's milk-based products as food in a NICU would object or question the safety of their child's food.

[30] Stang J, Hoss K, Story M. *Health Statements Made in Infant Formula Advertisements in Pregnancy and Early Parenting Magazines: A Content Analysis*, ICAN: Infant, Child, & Adolescent Nutrition, 2:1, 16-25 (2010).

54. Abbott has similarly sought to affect the knowledge and perceptions of the medical community and the health care providers administering their products as food in a NICU and lessen the likelihood that they would question the safety of cow's milk-based formulas for preterm infants or acknowledge the omission of NEC from product labeling or instructions.

55. These pervasive and deceptive marketing campaigns by Abbott, and other cow's milk-based formula manufacturers, have made products like Similac NeoSure ubiquitous in the NICU, when in reality, they pose a significant health risk to preterm infants like G.D.

D. Similac NeoSure is a Dangerous and Defective Product

56. Despite the overwhelming evidence that cow's milk-based products, like Similac NeoSure, cause or substantially increase the risk of developing NEC in preterm infants, Abbott failed to change the formulation of its cow's milk-based products or adequately warn the public of the risks by changing the packaging, guidelines, instructions, or warnings that accompany its products.

57. Upon information and belief, Abbott knew, or should have known, about the risk of NEC in preterm infants from cow's milk-based products, including Similac NeoSure.

58. Upon information and belief, Abbott knew about the risk of NEC from cow's milk-based products, including Similac NeoSure, for decades before G.D. was ever fed with Abbott's product and developed NEC.

59. Abbott, however, failed to warn consumers or the medical community about the risk of preterm infants developing NEC as a result of cow's milk-based nutrition products, including Similac NeoSure.

60. The packaging label for Similac NeoSure contains only the following warning, which entirely fails to mention NEC:

> Warning — Powdered infant formulas are not sterile and may be fed to premature infants or infants who might have immune problems only as directed by your baby's doctor. **Never use a microwave to warm formula.** Serious burns can result.

61. Likewise, *none* of Abbott's cow's milk-based nutrition products include warnings about the risk of NEC, and Abbott further fails to provide any guidance on how to avoid NEC while using its cow's milk-based products, including Similac NeoSure.

62. Abbott, nevertheless, markets, distributes, and sells its entire line of Similac NeoSure products as the "#1 PREMATURE INFANT FORMULA BRAND: And the #1 brand fed in the NICU."

63. Abbott has entirely failed to warn consumers that Similac NeoSure and other cow's milk-based nutrition products can significantly increase the risk that a preterm infant will develop NEC and suffer catastrophic injuries as occurred to G.D.

64. Upon information and belief, Abbott knew, or should have known, that Similac NeoSure was not safe for use by preterm infants because it could cause or significantly increase the risk of developing NEC.

65. Upon information and belief, Abbott did foresee, or should have foreseen, that Similac NeoSure would be used by preterm infants as it was used in the case of G.D., and knew or should have known that such use would significantly increase the risk of NEC, yet it took no steps to prevent such use.

66. Abbott negligently, recklessly, or intentionally marketed, distributed, and sold cow's milk-based nutrition products, including Similac NeoSure, without adequate warnings for preterm infants despite knowing that the products would be used by preterm infants and cause or significantly increase the risk of them developing NEC and suffering catastrophic injuries.

67. Upon information and belief, if Abbott adequately warned G.D.'s physicians or health care providers or made them aware of the facts and scientific evidence linking Similac NeoSure to NEC, they would not have allowed G.D. to be fed Similac NeoSure.

68. Upon information and belief, because Abbott markets, distributes, and sells Similac NeoSure as food for vulnerable preterm infants like G.D. with no warnings that it causes NEC, Similac NeoSure is viewed as safe by physicians, health care providers, and parents of preterm infants.

69. Upon information and belief, because Abbott markets, distributes, and sells Similac NeoSure as food for vulnerable premature infants and does not require warnings about NEC be given to parents or an informed consent be provided by hospitals or doctors, Similac NeoSure is viewed as safe by physicians, health care providers, and parents of preterm infants.

70. Similac NeoSure, however, is not safe for preterm infants, and did cause or significantly increase the risk of NEC in G.D. as a result of Abbott's negligent, reckless, or intentional failure to warn physicians, health care providers, or the parents of preterm infants, including Plaintiff.

D. Abbott Could Have Provided Adequate Warnings – But Chose Not To

71. Infant formulas, including Similac NeoSure, are defined as food under the Federal Food Drug, and Cosmetic Act ("FDA Act"),[31] and are federally regulated by The Infant Formula Act ("IFA") [32] and its implementing regulations.[33]

[31] "The term 'infant formula' means a food which purports to be or is represented for special dietary use solely as a food for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk." 21 U.S.C. § 321(z).

[32] 21 U.S.C. § 350a.

[33] 21 C.F.R. §106-07.

72. The IFA lays out certain requirements and procedures that infant formula manufacturers, like Abbott, must follow before introducing infant formula products into interstate commerce, including, minimum, or sometimes maximum, nutrient requirements for infant formulas; the quality factors and manufacturing practices that manufacturers of infant formulas must follow; and registration and notification requirements for infant formula manufacturers.

73. Infant formula manufacturers are not subject to the same regulatory regime as manufacturers of prescription or generic drugs under the FDA Act.[34]

74. Under the FDA Act, drug or medical device manufacturers must obtain pre-approval for their products and warning labels before bringing their products to market, so any unilateral change in a drug's composition or product labeling would violate federal law.

75. FDA does not "approve" infant formula products.

76. The relevant provisions of the IFA governing infant formulas do not prevent an infant formula manufacturer, like Abbott, from altering the formulation or labeling of a formula product.

77. If Abbott wished to market an infant formula product with a major change in its formulation, it must simply provide FDA with a notification about the major change and assurances that its formula will meet all the necessary requirement of federal law.

78. If Abbott wished to update the labeling of an infant formula product, like Similac NeoSure, to warn of specific adverse risks such as NEC, it could do so.

79. If Abbott wished to market Similac NeoSure with a major change in formulation before G.D. was fed Similac NeoSure, it could have done so and provided FDA with a notification about the major change and assurances that the new formulation met the necessary requirements.

[34] 21 U.S.C. § 301 *et seq.*

80. If Abbott wished to update the labeling of Similac NeoSure to warn of specific adverse risks, including NEC, prior to when G.D. was fed Similac NeoSure, it could have done so.

81. Abbott however failed at all times to update the formulation of Similac NeoSure to render it safer for premature infants and decrease the risk NEC or update the label of Similac NeoSure to warn of the risk of NEC.

82. Instead of changing the formulation of Similac NeoSure to make it safer for preterm infants, or providing adequate warnings for preterm infants by updating the label advise about the risk of NEC, Abbott aggressively marketed Similac NeoSure and its line of cow's milk-based nutrition products as intended for preterm infants.

83. Abbott has promoted cow's milk-based nutrition products, including Similac NeoSure, as intended for premature infants, like G.D., and more beneficial than harmful for them.

84. Abbott has marketed cow's milk-based nutrition products, including Similac NeoSure, as safe and beneficial for premature infants like G.D.

85. Notwithstanding the overwhelming scientific evidence establishing the significant risks and dangers from NEC that cow's milk-based nutrition products pose for premature infants, Abbott has marketed and continues to market its cow's milk-based products, including Similac NeoSure, as an equally safe alternative to human milk and human milk-based products, and has promoted its products as necessary for additional nutrition and growth in preterm infants.

86. Abbott has and continues to specifically market its cow's milk-based nutrition products, including Similac NeoSure, as necessary for the growth and development of preterm infants, when indeed these products pose a known and substantial risk of NEC to preterm infants.

87. Abbott markets and sells its cow's milk-based nutrition products, including Similac NeoSure, specifically to premature infants and their parents, physicians, or health care providers.

88. Abbott markets and sells cow's milk-based nutrition products, including Similac NeoSure, under the guise of being safe for preterm infants and despite knowing the significant health risks posed to preterm infants by consuming these products.

89. Abbott entirely fails to mention in its promotional or advertising content that cow's milk-based nutrition products, including Similac NeoSure, cause or significantly increase the risk of NEC in preterm infants.

E. Feasible, Safer Alternative Formula Design Was Known and Available

90. Abbott's cow's milk-based nutrition products, including Similac NeoSure, are unreasonably dangerous and create a substantial likelihood of harm to preterm infants, including G.D.

91. At the time Abbott researched, developed, designed, manufactured, marketed, distributed, and sold the Similac NeoSure used by G.D., a feasible, safer alternative design for the formulation of Similac NeoSure was known and available to Abbott, including, but not limited to, a product formulation using pasteurized human milk instead of cow's milk.

92. Prolacta Bioscience, a California-based life sciences company, manufactures and sells human milk-based feeding products specifically designed for preterm infants that do not contain cow's milk.

93. Human milk-based nutrition products, including those manufactured and sold by Prolacta Bioscience, provide all the necessary nutrition for growth and development for preterm infants that cow's milk-based nutrition products provide, without the same unreasonably dangerous adverse effects or substantial likelihood of harm resulting from NEC.

94. Upon information and belief, Abbott knew or should have known that cow's milk-based nutrition products, including Similac NeoSure, cause or substantially increase the risk of NEC, while human milk-based nutrition products do not.

95. Upon information and belief, Abbott knew or should have known that human milk-based nutrition products have the same utility and are as acceptable to consumers and preterm infants as cow's milk-based nutrition products, but do not have the unreasonably dangerous effects or substantial risk of harm resulting from NEC that is associated with cow's milk-based nutrition products, like Similac NeoSure.

96. Upon information and belief, Abbott was aware of these unreasonable and substantial risks, but instead of warning consumers, including Plaintiff, G.D., or G.D.'s physicians and health care providers of the true risks, or removing cow's milk-based nutrition products from the market altogether, Abbott continued to use cow's milk in its nutrition products intended for preterm infants, including Similac NeoSure, and permitted infants like G.D. to suffer the foreseeable consequences and develop NEC.

F. G.D. Consumed a Dangerous and Defective Product in the NICU

97. Plaintiff gave birth to G.D. at 26 weeks and 3 days at Good Samaritan Hospital in West Islip, New York in 2020.

98. G.D. weighed approximately 765 grams or 1.7 pounds at the time of his birth, classifying him as a very low birth weight preterm infant.

99. G.D. was unable to breathe on his own requiring resuscitation in the delivery room, and was transferred shortly thereafter to the NICU for further care and evaluation.

100. While in the NICU, Good Samaritan hospital staff fed Similac NeoSure to G.D.

101. Within days of consuming Similac NeoSure, G.D. developed NEC, requiring him to undergo critical surgical interventions and suffer life-altering complications.

102. As a result of developing NEC, G.D. required and underwent successive critical surgical interventions, including insertion of a peritoneal drain in September 2020; laparotomy with intestinal resection, Broviac catheter placement, and drain insertion in October 2020; and laparotomy with ileostomy closure and bilateral inguinal hernia repair in December 2020.

103. As a result of suffering NEC, and undergoing the aforementioned surgical procedures, G.D. lost a substantial amount of his intestines, resulting in continued gastrointestinal limitations that have caused or contributed to development delays and failure to thrive, which will affect him for the rest of his life.

104. Plaintiff was never told or informed that Similac NeoSure contained cow's milk.

105. Upon information and belief, neither G.D.'s physicians nor health care providers were ever told or informed that Similac NeoSure contained cow's milk.

106. Plaintiff was never told or informed that Similac NeoSure, or other cow's milk-based nutrition products, could cause G.D. to develop or substantially increase the risk of him developing NEC.

107. Upon information and belief, neither G.D.'s physicians nor health care providers were ever told or informed that Similac NeoSure, or other cow's milk-based nutrition products, could cause G.D. to develop NEC or substantially increase the risk of him developing NEC.

108. Plaintiff was never told or informed that Similac NeoSure could catastrophically harm G.D.

109. Upon information and belief, neither G.D.'s physicians nor health care providers were ever told or informed that Similac NeoSure could catastrophically harm G.D.

110. Plaintiff was never told or informed about the scientific evidence or research showing that cow's milk-based nutrition products, like Similac NeoSure, could cause or substantially increase the risk of NEC in preterm infants and therefore were extremely dangerous to G.D.

111. Upon information and belief, neither G.D.'s physicians nor health care providers were ever told or informed about the scientific evidence and research showing that cow's milk-based nutrition products, like Similac NeoSure, could cause or substantially increase the risk of NEC in preterm infants and therefore were extremely dangerous to G.D.

112. If Abbott adequately warned Plaintiff or made her aware of the facts and scientific evidence linking Similac NeoSure to NEC in preterm infants, Plaintiff would not have allowed G.D. to be fed Similac NeoSure.

113. If Abbott adequately warned G.D.'s physicians and health care providers, or made them aware of the facts and scientific evidence linking Similac NeoSure to NEC in preterm infants, G.D.'s physicians and health care providers would not have allowed G.D. to be fed Similac NeoSure.

114. Accordingly, as a direct and proximate cause of Abbott's use of cow's milk in the formulation of cow's milk-based nutrition products intended for preterm infants, including Similac NeoSure, and its failure to warn Plaintiff or G.D.'s physicians and health care providers of the risk of its products causing or significantly increasing the risk of NEC, G.D. suffered NEC, requiring multiple surgical interventions, and resulting in catastrophic injuries and life-altering limitations.

EQUITABLE TOLLING OF STATUTE OF LIMITATIONS

115. The running of any statute of limitations has been equitably tolled by reason of Abbott's fraudulent concealment or omissions of critical safety information. Through affirmative

misrepresentations or omissions, Abbott actively concealed from Plaintiff and her physicians and health care providers the true risks associated with cow's milk-based nutrition products, including Similac NeoSure.

116. As a result of Abbott's actions, Plaintiff was unaware, and could not have reasonably known or learned through reasonable diligence, that G.D. had been exposed to the risks and harms set forth herein and that those risks and harms were the direct and proximate result of Abbott's acts and omissions.

CAUSES OF ACTION

COUNT I
STRICT LIABILITY-FAILURE TO WARN

117. Plaintiff repeats, reiterates, and re-alleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

118. At all relevant times, Abbott engaged in the business of researching, developing, designing, manufacturing, marketing, distributing, and selling cow's milk-based nutrition products, including the Similac NeoSure brand product consumed by G.D., which are defective and unreasonable dangerous to preterm infant users, like G.D., because they cause or significantly increase the risk of NEC and do not contain adequate warnings, instructions, or guidelines concerning their dangerous characteristics.

119. At the time Abbott researched, developed, designed, manufactured, marketed, distributed, sold and otherwise released cow's milk-based nutrition products into the stream of commerce, Abbott knew or should have known that these products, including the Similac NeoSure consumed by G.D., presented an unreasonable danger to preterm infant users when used as intended and in a reasonably anticipated manner.

120. Specifically, at all relevant times, Abbott knew, or should have known, that its cow's milk-based nutrition products, including Similac NeoSure, pose a significant health risk in that the they cause or significantly increase the risk of NEC in preterm infants and do not contain adequate warnings, instructions, or guidelines concerning their dangerous characteristics.

121. At all relevant times, Abbott knew, or should have known, that cow's milk-based nutrition products created significant risks of serious bodily harm to consumers, including G.D., as alleged herein, and Abbott failed to adequately warn reasonably foreseeable preterm infant users, their parents, physicians, or health care providers of the inherent risks of NEC, requiring surgical treatment, and resulting in catastrophic injuries associated with use of the subject cow's milk-based nutrition products .

122. At all relevant times, Abbott had a duty to properly research, develop, design, manufacture, market, distribute, and sell cow's milk-based nutrition products, including the Similac NeoSure consumed by G.D., which included providing proper warnings, and taking such steps as necessary to ensure the subject products did not cause users, like G.D., to suffer from unreasonable and dangerous risks such as NEC.

123. Abbott, as a researcher, developer, designer, manufacturer, marketer, distributor, and seller of infant nutrition products, is held to the knowledge of an expert in the field, and had a continuing duty to warn the parents, physicians, or health care providers of preterm infant users, including G.D., of the risks associated with using cow's milk-based nutrition products.

124. Abbott had a duty to warn Plaintiff of the risks of harm to G.D. resulting from him consuming cow's milk-based nutrition products, including Similac NeoSure.

125. Abbott had a duty to warn G.D.'s physicians or health care providers of the risks of harm to G.D. resulting from him consuming cow's milk-based nutrition products, including Similac NeoSure.

126. At all relevant times, Abbott could have provided proper warnings or instructions regarding the full and complete risks concerning cow's milk-based nutrition products, including Similac NeoSure, because Abbott knew, or should have known, of the unreasonable risks of harm from NEC associated with consuming cow's milk-based nutrition products.

127. At all relevant times, Abbott failed and deliberately refused to investigate, study, test, promote the safety, or minimize the dangers to preterm infants, including G.D., who would foreseeably use or be harmed by its cow's milk-based nutrition products.

128. Plaintiff permitted G.D. to use and be exposed to Abbott's cow's milk-based nutrition products, including Similac NeoSure, without knowledge of the dangerous characteristics of these products.

129. G.D. used and was exposed to Abbott's cow's milk-based nutrition products, including Similac NeoSure, without knowledge of the dangerous characteristics of these products.

130. Despite Abbott's duty or obligation to unilaterally strengthen the warnings to prevent foreseeable or preventable harm to users of its cow's milk-based nutrition products, Abbott instead actively concealed knowledge of the true risks concerning preterm infants developing NEC as a result of using of these products for their intended purpose.

131. At all relevant times, Plaintiff permitted G.D. to use or be exposed to Abbott's cow's milk-based nutrition products, including Similac NeoSure, while G.D. used them for their intended or reasonably foreseeable purpose and without knowledge of their dangerous characteristics.

132. At all relevant times, G.D. used or was exposed to Abbott's cow's milk-based nutrition products, including Similac NeoSure, while using them for their intended or reasonably foreseeable purpose and without knowledge of their dangerous characteristics.

133. Neither Plaintiff nor G.D. could have reasonably discovered the defects and risks associated with Similac NeoSure prior to or at the time G.D. used it, and relied upon the skill, superior knowledge, and judgment of Abbott to know about and disclose to Plaintiff or G.D.'s physicians and health care providers the serious health risks associated with preterm infants using cow's milk-based nutrition products.

134. Abbott knew or should have known that failing to disseminate warnings or instructions regarding the risk preterm infants developing NEC and suffering severe and life-threatening injuries as a result of consuming cow's milk-based nutrition products, including Similac NeoSure, rendered these products unreasonably dangerous and unfit for their ordinary, intended, and reasonably foreseeable use.

135. The information Abbott did provide or communicate to consumers, physicians, or health care providers entirely failed to contain relevant or adequate warnings or precautions that would have enabled consumers, such as Plaintiff or G.D.'s physicians and health care providers, to safely feed cow's milk-based nutrition products to preterm infants.

136. The information Abbott provided or communicated to consumers, physicians, or health care providers entirely failed to contain relevant or adequate warnings or precautions that would have enabled consumers, such as Plaintiff or G.D.'s physicians or health care providers, to make an informed decision as to whether to administer cow's milk-based nutrition products to preterm infants, such as G.D., based on weighing the potential risks and benefits of the products.

137. Abbott failed to disseminate information regarding the true and complete risks and otherwise disseminated information that was inaccurate, incomplete, false, and misleading, and which failed to communicate accurately or adequately the risk of preterm infants developing NEC as a result of consuming its cow's milk-based nutrition products.

138. Abbott knew or should have known of the unreasonable risks from preterm infants using cow's milk-based nutrition products, and downplayed or otherwise suppressed information or research about the risks and dangers of these products.

139. Abbott was able, and in accordance with federal law, to disclose the known risks associated with the cow's milk-based nutrition products, including the Similac NeoSure consumed by G.D., through product package label changes, public announcements, promotions, advertisements, and other public information sources.

140. Abbott is therefore liable for the injuries suffered by Plaintiff and G.D. caused by its own negligent, reckless, or willful failure to provide adequate warnings, instructions, or relevant information and data regarding the risks associated with preterm infants consuming cow's milk-based nutrition products, including Similac NeoSure.

141. Had Abbott provided adequate warnings, instructions, or relevant information, and disseminated the risks associated with the subject devices, Plaintiff could have obtained or used alternative nutrition products to safely provide G.D. with nourishment and support his growth and development.

142. As a direct and proximate result of Abbott placing the dangerous and defective cow's milk-based nutrition products, including Similac NeoSure, into the stream of commerce, Plaintiff and G.D. were injured and sustained damages and pecuniary loss in a sum exceeding the jurisdictional minimum of this Court in an amount to be determined at trial.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and such other relief as this Court deems just and proper.

COUNT II
STRICT LIABILITY-DESIGN DEFECT

143. Plaintiff repeats, reiterates, and re-alleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

144. Abbott's cow's milk-based nutrition products, including Similac NeoSure, are inherently dangerous and defective, unfit and unsafe for their intended and reasonably foreseeable uses by preterm infants, and do not meet or perform to the expectations of users or their parents, physicians, or health care providers.

145. The design of Abbott's cow's milk-based nutrition products, including Similac NeoSure, use a design incorporating cow's milk in the product formulation, which is unreasonably dangerous and defective and causes or significantly increases the risk of NEC in preterm infants.

146. The digestion of cow's milk by preterm infants is known to cause or significantly increase the risk of NEC, requiring surgical treatment, and resulting in catastrophic injuries.

147. Abbott's cow's milk-based nutrition products, including Similac NeoSure, are defective in design in that their risk of harm exceeds any claimed benefits.

148. Abbott's cow's milk-based nutrition products, including Similac NeoSure, do not perform as an ordinary consumer would expect.

149. The inherent risks, hazards, and dangers associated with the design of Abbott's cow's milk-based nutrition products, including Similac NeoSure, incorporating cow's milk in the product formulation, renders these products unreasonably dangerous for preterm infants.

150. The risk-benefit profile of Abbott's cow's milk-based nutrition products, including Similac NeoSure, is unreasonable for preterm infant users, and these products should have either incorporated an alternative design without cow's milk, or should not have been sold on the market.

151. In fact, there are other similar nutrition products intended for preterm infants that do not contain cow's milk or result in the ingestion of cow's milk or other substances that cause or significantly increase the risk of NEC.

152. Safer, alternative sources of nutrition, such as human milk or human milk-based formulas or fortifiers, were available to Plaintiff, G.D., and G.D.'s physicians and health care providers and did not carry the same risks as Abbott's cow's milk-based nutrition products, including Similac NeoSure, and did not have the unreasonable risk of harm from NEC associated with Abbott's cow's based-milk products and their unsafe use of cow's milk in the product formulation.

153. As a result of the foregoing design defects, Abbott created risks to the health and safety to preterm infant users of its cow's milk-based nutrition products, including G.D., that were far more significant and devastating than the risks posed by other nutrition products available to Plaintiff, G.D., or G.D.'s physicians and health care providers, and which far outweigh the utility of cow's milk-based nutrition products.

154. Accordingly, the design of Abbott's cow's milk-based nutrition products, including Similac NeoSure, renders these products not reasonably fit, suitable, or safe for their intended purpose as nutrition products for preterm infants.

155. Abbott negligently, recklessly, or intentionally designed cow's milk-based nutrition products, including Similac NeoSure, with wanton and willful disregard for the rights and health

of G.D., and other preterm infants, and did so with malice, placing its economic interests above the health and safety of G.D. and others.

156. As a direct and proximate result of the design of Abbott's cow's milk-based nutrition products, including Similac NeoSure, Plaintiff and G.D. were injured and sustained damages and pecuniary loss in a sum exceeding the jurisdictional minimum of this Court in an amount to be determined at trial.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and such other relief as this Court deems just and proper.

COUNT III
NEGLIGENCE

157. Plaintiff repeats, reiterates, and re-alleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

158. Abbott, as a researcher, developer, designer, manufacturer, marketer, distributor, and seller of cow's milk-based nutrition products, including Similac NeoSure, owed a duty to the consuming public in general, including Plaintiff and G.D., to exercise reasonable care design, test, manufacture, inspect, and distribute products free of unreasonable risk of harm to foreseeable consumers and users using these products in their intended manner.

159. Abbott is held to the knowledge and skill of an expert in the research, development, design, manufacture, marketing, distribution, and sale of cow's milk-based nutrition products, including Similac NeoSure, and has a duty to keep abreast of any relevant scientific discoveries, advances, or literature pertaining to its products, and is presumed to know the results of any such relevant knowledge.

160. Abbott had a duty to exercise reasonable care in designing nutrition products in such a manner that they were not dangerous, harmful, injurious, or pose an unreasonable risk to intended preterm infant users, such as G.D.

161. Abbott's cow's milk-based nutrition products are designed and intended to be used by preterm infants, and Abbott knew, or by the exercise of reasonable care should have known, that its cow's milk-based nutrition products, including Similac NeoSure, are dangerous, harmful and injurious when used by preterm infants in a reasonably foreseeable manner as a result of the incorporation of cow's milk in the product formulation.

162. Abbott breached its duty and failed to use reasonable care by researching, developing, designing, manufacturing, marketing, distributing, and selling cow's milk-based nutrition products, including Similac NeoSure, with a formulation intended for preterm infants that incorporates cow's milk, which when ingested by preterm infants causes or significantly increases the risk of NEC and severe injuries, and by failing to warn consumers or users of these significant risks.

163. Abbott negligently or recklessly researched, developed, designed, manufactured, marketed, distributed, and sold cow's milk-based nutrition products, including the subject Similac NeoSure consumed by G.D., intended for preterm infants, and in doing so, breached its duty to Plaintiff, G.D., and the consuming public in the following ways:

a) Researching, developing, designing, manufacturing, marketing, distributing and selling nutrition products, such as Similac NeoSure, which expose preterm infants to latent and not obvious dangers when used in a foreseeable and intended manner;

b) Researching, developing, designing, manufacturing, marketing, distributing and selling nutrition products, such as Similac NeoSure, which were not reasonably safe for their intended purpose and subjected preterm infants, including G.D., to the risk of serious and

life-threatening injuries due to the inherent defects of the products, namely the incorporation of cow's milk in the product formulation;

c) Failing to continuously and vigorously study cow's milk-based nutrition products, including Similac NeoSure, in order to determine their true, accurate, and complete safety profiles for preterm infants, such as G.D.;

d) Failing to collect or review available data to determine if cow's milk-based nutrition products, including Similac NeoSure, were safe for preterm infants, such as G.D.;

e) Failing to utilize reasonable care to inspect or test cow's milk-based nutrition products, including Similac NeoSure, post-market to evaluate their safety for preterm infants;

f) Failing to collect or review data to determine when and how cow's milk-based nutrition products, including Similac NeoSure, could be used safely by preterm infants, such as G.D.;

g) Failing to conduct testing, studies, or trials to determine if cow's milk-based nutrition products, including Similac NeoSure, were safe for preterm infants, such as G.D.;

h) Failing to collect or review data to determine how, when, or under what conditions cow's milk-based nutrition products, including Similac NeoSure, could be safely used by preterm infants, such as G.D.;

i) Failing to utilize peer reviewed research to develop true, accurate, and complete product labeling, instructions, guidelines, or warnings for cow's milk-based nutrition products, including Similac NeoSure;

j) Failing to develop evidence-based labeling, instructions, guidelines, or warnings to decrease the risk of cow's milk-based nutrition products, such as Similac NeoSure, causing NEC and severe injuries to preterm infants, including G.D.;

k) Failing to provide evidence-based labeling, instructions, guidelines, or warnings to consumers or users, such as Plaintiff, to decrease or prevent the risk of cow's milk-based nutrition products, including Similac NeoSure, causing NEC and severe injuries to preterm infants, such as G.D.;

l) Failing to provide evidence-based labeling, instructions, guidelines, or warnings to consumers or users, including Plaintiff, on when or how a preterm infant, such as G.D., should be transitioned to cow's milk-based nutrition products in a manner that is safe and consistent with accepted medical science;

m) Failing to provide warnings reasonably calculated or expected to reach the parents of a preterm infant regarding the inherent risk or dangers to preterm infants resulting from cow's milk-based nutrition products, including Similac NeoSure;

n) Failing to provide labeling, instructions, guidelines, or warnings to health care providers and other hospital or NICU staff directing that parent should be provided information necessary to make an informed choice about whether to allow their preterm infant be fed cow's milk-based nutrition products, including Similac NeoSure, notwithstanding the specific and significant risk of NEC;

o) Failing to utilize feasible and technically available alternative designs for the formulation of nutrition products intended for preterm infants, including formulas or fortifiers, that do not incorporate cow's milk; and

p) Failing to utilize feasible and technically available manufacturing processes for the production of nutrition products intended for preterm infants, such as formulas or fortifiers, that do not incorporate cow's milk.

164. Abbott knew or should have known that its cow's milk-based nutrition product, Similac NeoSure, was to be used and consumed by G.D. as food.

165. Abbott knew, or should have known, that the use of Similac NeoSure was unreasonably dangerous for a preterm infant like G.D., in that it significantly increased the risk of NEC and severe injuries due to the incorporation of cow's milk in the product formulation and did not carry appropriate labeling, instructions, guidelines, or warnings regarding these risks.

166. Abbott knew, or should have known, that Similac NeoSure was not reasonably fit, suitable, or safe for its intended purpose and should not have been sold on the market or otherwise made available to G.D.

167. Plaintiff would not have authorized, chosen, or allowed G.D. to be fed with Similac NeoSure if she knew of the defects and the complete risks associated with the use of cow's milk-based nutrition products.

168. G.D.'s physicians and health care providers would not have authorized, chosen, or allowed G.D. to be fed with Similac NeoSure if they knew of the defects and the complete risks associated with the use of cow's milk-based nutrition products.

169. Abbott negligently deprived both Plaintiff and G.D.'s physicians and health care providers of reasonable notice or warning regarding the complete risks posed by Similac NeoSure.

170. Abbott instead used pervasive and aggressive marketing campaigns and promotions to create a false sense of security and misperceptions amongst the consuming public regarding the inherent and significant risks its cow's milk-based nutrition products, including Similac NeoSure.

171. Abbott failed to act in a reasonably prudent manner as a researcher, developer, designer, manufacturer, marketer, distributor, and seller of cow's milk-based nutrition products, including Similac NeoSure, and breached its duty of care to Plaintiff, G.D., and the consuming public.

172. As a direct and proximate cause of the Abbott's aforementioned negligence, Plaintiff and G.D. were injured and sustained damages and pecuniary loss in a sum exceeding the jurisdictional minimum of this Court in an amount to be determined at trial.

WHEREFORE, Plaintiff demands judgement against Defendant for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and such other relief as this Court deems just and proper.

COUNT VI
PUNITIVE DAMAGES

173. Plaintiff repeats, reiterates, and re-alleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

174. Abbott knew or should have known that its cow's milk-based nutrition products, including Similac NeoSure, were inherently dangerous with respect to causing or significantly increasing the risk of NEC in preterm infants.

175. Abbott knew or should have known that its cow's milk-based nutrition products were inherently more dangerous with respect to the aforesaid risks than alternative nutrition products on the market.

176. Abbott attempted to and did misrepresent facts concerning the risks and safety of its cow's milk-based nutrition products, including Similac NeoSure.

177. Abbott's misrepresentations included knowingly withholding material information concerning the safety of its cow's milk-based nutrition products from consumers and the medical community, including Plaintiff, G.D. and G.D.'s physicians or health care providers.

178. Abbott knew and recklessly disregarded the fact that preterm infants using cow's milk-based nutrition products, including Similac NeoSure, for their intended purposes could cause or significantly increase the risk of NEC.

179. Notwithstanding the foregoing, Abbott has marketed cow's milk-based nutrition products, including Similac NeoSure, without disclosing the aforesaid health and safety risks when there were safer alternative nutrition products that did not pose the same or similar health and safety risks.

180. Abbott knew of the defective and unreasonably dangerous nature of cow's milk-based nutrition products, but continued to research, develop, design, manufacture, market,

distribute, and sell these products in conscious, reckless, or negligent disregard of the foreseeable harm in order to maximize sales and profits at the expense of the health and safety of preterm infant users, including G.D.

181. Abbott's intentional, reckless, fraudulent, and malicious failure to disclose information regarding the health and safety risks of cow's milk-based nutrition products, including Similac NeoSure, deprived Plaintiff and G.D.'s physicians and health care providers the necessary information to enable them to weigh the true risks of using Abbott's cow's milk-based nutrition products against their benefits.

182. As a direct and proximate result of Abbott's conscious and deliberate disregard for the rights and safety of preterm infants, Plaintiff and G.D. suffered severe personal injuries and sustained damages and pecuniary loss in a sum exceeding the jurisdictional minimum of this Court in an amount to be determined at trial.

183. The aforesaid conduct of Abbott was committed with knowing, conscious, and deliberate disregard for the rights and safety of preterm infant users, including G.D., thereby entitling Plaintiff and G.D. to punitive damages in an amount appropriate to punish Abbott and deter them from similar conduct in the future.

WHEREFORE, Plaintiff demands judgement against Defendant for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and such other relief as this Court deems just and proper.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendant for damages to which she is entitled by law, as well as all costs of this action, interest and attorneys' fees, to the full extent of the law, including:

a) Judgment for Plaintiff and against Defendant;

b) Damages to compensate G.D. for his injuries, economic losses, and pain and suffering;

c) Damages to compensate Plaintiff for her injuries, economic losses, and pain and suffering;

d) Punitive damages, attorneys' fees, and costs;

e) Prejudgment interest at the lawful rate;

f) Plaintiff's reasonable attorneys' fees; and

g) For any other relief as this Court deems just and proper.

JURY DEMAND

Plaintiff demands a trial by jury on all issues so triable.

Dated: March 18, 2022

Respectfully Submitted,

PARKER WAICHMAN LLP

/s/Christine M. Durant
Christine M. Durant
Raymond C. Silverman
6 Harbor Park Drive
Port Washington, NY 11050
Phone: (516) 466-6500
Fax: (516) 466-6665
cdurant@yourlawyer.com
rsilverman@yourlawyer.com